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HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE SYOSSET, NY 11791			EXAMINER WONG, LESTLIE A	
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte RUY TCHAO

Appeal 2007-4229
Application 09/472,490¹
Patent 5,601,997
Technology Center 1700

Decided: January 28, 2008

Before TEDDY S. GRON, ADRIENE LEPIANE HANLON, and
CAROL A. SPIEGEL, *Administrative Patent Judges*.

SPIEGEL, *Administrative Patent Judge*.

DECISION ON APPEAL

INTRODUCTION

¹ Application 09/472,490, filed 23 December 1999, is said to be a continuation of Application 09/159,427, filed 23 September 1998, as a reissue of Patent 5,601,997 ("the '997 patent"), which issued 11 February 1997, based on Application 08/383,058, filed 3 February 1995. The real party-in-interest is said to be Ruy Tchao (APPEAL BRIEF PURSUANT TO 37 C.F.R. §41.37 IN RESPONSE TO NOTICE OF NON-COMPLIANT BRIEF, filed 8 December 2006 ("App. Br.") at 3).

Ruy Tchao ("Appellant") appeals under 35 U.S.C. § 134 from the Examiner's final rejection of claims 46-50, all of the pending claims. Claim 49 is also objected to as being dependent upon a rejected base claim (Ans.² 5). We have jurisdiction under 35 U.S.C. § 6(b). We AFFIRM.

SUBJECT MATTER ON APPEAL

The claims on appeal are directed to a cell migration assay comprising measuring the movement of cells across a radiation opaque membrane, wherein the assay does not destroy the cells being measured. Claim 46, the sole independent claim, is illustrative and reads (App. Br. 18):

A cell migration assay procedure comprising
measuring the migration of cells across a radiation
opaque membrane wherein said procedure is non-
destructive of said cells.

THE REJECTIONS

Claims 46-50 stand rejected for obviousness-type double patenting of claims 1-19 of US Patent RE38,863 E.³ "This rejection is not being appealed as, if the claims are otherwise found to be allowable, an appropriate terminal disclaimer will be filed" by Appellant (App. Br. 4; see also App. Br. 16). Therefore, we AFFIRM the rejection of claims 46-50 for obviousness-type double patenting of claims 1-19 of RE38,863 E since a proper terminal disclaimer has not yet been filed by Appellant.

² Examiner's Answer mailed 23 February 2007 ("Ans.").

³ According to the Examiner, claims 46-50 stand "provisionally rejected under the judicially created doctrine of obviousness-type double patenting ...over claims 1-15 and 38-41 of copending Application No. 09/966,831" (Ans. 4). Application No. 09/966,831 issued as reissue patent US RE38,863 E on 1 November 2005. Thus, this is no longer a provisional rejection.

Claims 46-50 stand rejected under 35 U.S.C. § 251 as based on a defective declaration (Ans. 4). "This rejection is also not being appealed as, if the claims are found to be otherwise allowable, an appropriate supplemental oath/declaration pursuant to 37 C.F.R. § 1.75(b)(1) will be filed" by Appellant (App. Br. 4; see also App. Br. 16). Therefore, we AFFIRM the rejection of claims 46-50 under § 251 as based on a defective reissue oath/declaration since a proper oath/declaration has not yet been filed by Appellant.

Claims 46-48 and 50 stand rejected under 35 U.S.C. § 112, first paragraph, as not enabled throughout their full scope (Ans. 5); and, under 35 U.S.C. § 251 as improperly broadening the scope of the claims of the '997 patent (Ans. 6). We discuss these last two rejections below.

FINDINGS OF FACT

The following findings of fact ("FF") are supported by a preponderance of the evidence of record.

- [1] Originally issued claim 15 of the '997 patent reads, "A chemotaxis assay procedure comprising measuring the migration of cells across a radiation opaque membrane, wherein said procedure is non-destructive of said cells" (emphasis added).
- [2] Claim 46 of the reissue application on appeal differs from originally issued claim 15 of the '997 patent only in its preamble, which recites "A cell migration assay procedure."
- [3] According to the '997 patent,⁴ such radiation opaque membranes permit the measurement of radiation emitted from labeled cells that have migrated

⁴ We cite the '997 patent in lieu of the reissue application on appeal.

through the radiation opaque membrane without interference from radiation emitted from the labeled cells that have not migrated, without the need to remove the non-migrated cells from the radiation opaque membrane. This is a significant advantage of the present invention over the prior art procedures, not only because it avoids the tedious steps of removing the filter, and scraping the non-migrated cells from the filter, but also because it is non-destructive of the cell sample and thus permits repeated measurements of the same test sample at different time intervals. ['997 patent 5:62 through 6:9.]

- [4] In one embodiment, the '997 patent describes using a radiation opaque porous membrane to separate a well into two chambers, placing labeled cells into one chamber and a chemical agent into the other. Chemotaxis is said to cause labeled cells to migrate through the membrane into the other chamber in response to the chemical agent, wherein the amount of label on that side of the membrane, and thus the amount of migrated cells, can be measured at predetermined intervals ('997 patent 3:42 through 4:38).
- [5] The '997 patent defines chemotaxis as "the orientation or movement of an organism or cell in relation to a chemical agent" ('997 patent 1:14-15).
- [6] Both Appellant and the Examiner acknowledge that chemotaxis is but one method known for use in effecting cell migration (App. Br. 9; Ans. 5-6).

- [7] According to the Examiner, the disclosure of the '997 patent is limited to non-destructive chemotaxis assays because it does not disclose cell migration in response to any other stimulus (Ans. 5-6).
- [8] Further according to the Examiner, it would require "extensive experimentation" to use other methods of inducing cell migration, such as phototaxis, electrotaxis, or geotaxis, in response to an agent other than a chemical agent (Ans. 6).⁵
- [9] The Examiner concludes that the reissue claims have improperly broadened the scope of the originally issued claims because "Appellant does not teach any and all types of non-destructive assays or any and all types of inducing agents" (Ans. 6).
- [10] Appellant argues that the operative assay measurement is cell migration and chemotaxis is only one technique known to induce cell migration (App. Br. 9-10).
- [11] In other words, Appellant argues that use of a radiation opaque membrane as recited in claim 46 is independent of the particular stimulant causing the cells to migrate therethrough (App. Br. 10).
- [12] According to Appellant, so long as the membrane used in the assays has the properties described in the specification, no undue experimentation would have been necessary to practice the claimed steps in any cell migration assay (App. Br. 13).
- [13] Thus, Appellant submits that the originally filed application describes and enables a non-destructive cell migration assay

⁵ Taxis is the response of a cell or an organism to a directional (attractive or repulsive) stimulus. For example, the stimuli for chemotaxis, geotaxis, electrotaxis and phototaxis are a chemical, gravity, electric current and light, respectively.

procedure as recited in the appealed claims and that the requirements of § 251 have been satisfied (App. Br. 15).

DISCUSSION

A. Enablement

"When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application. . .". *In re Wright*, 999 F.2d 1557, 1561-62 (Fed. Cir. 1993). "That some experimentation is necessary does not constitute a lack of enablement; the amount of experimentation, however, must not be unduly extensive." *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1212 (Fed. Cir. 1991). "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). A number of factors are relevant to whether undue experimentation would have been required to practice the claimed invention, including "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *Id.*, 858 F.2d at 737.

According to the Examiner, "extensive experimentation" would have been required to enable the full scope of the claims 46-48 and 50

because the '997 patent specification only discloses cell migration in response to a chemical stimulus (FFs 7-8). The Examiner did not characterize the extent of experimentation as undue. The Examiner did not provide a sufficient factual basis for concluding that undue experimentation would have been required, e.g., that a person of ordinary skill in the art, using the knowledge available to such a person and the disclosure of the '997 patent specification, could not have made and used the claimed invention. "Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching [of how to make and use the full scope of the claimed invention] is provided through broad terminology or illustrative examples." *In re Wright*, 999 F.2d at 1561 (Fed. Cir. 1993).

Therefore, we REVERSE the Examiner's rejection of claims 46-48 and 50 under § 112, first paragraph, for lack of enablement.

B. Broadening reissue claims

"Section 251 allows patentees to correct 'errors' made during prosecution, such as claiming less than the patentee had a right to claim." *In re Clement*, 131 F.3d 1464, 1468 (Fed. Cir. 1997). In essence, the position of the Examiner is that Appellant has no right to the subject matter of reissue claims 46-48 and 50 because the '997 patent specification would not have enabled the full scope of these claims. Since the Examiner has failed to establish that the disclosure of the '997 patent specification would not have enabled the full scope of reissue claims 46-48 and 50, we also REVERSE the Examiner's rejection of claims 46-48 and 50 under § 251.

ORDER

Upon consideration of the record and for the reasons given, it is ORDERED that the decision of the Examiner rejecting claims 46-50 under the judicially created doctrine of obviousness patenting over claims 1-19 of RE38,383 E is AFFIRMED;

FURTHER ORDERED that the decision of the Examiner rejecting claims 46-50 under 35 U.S.C. § 251 as based on a defective reissue oath/declaration is AFFIRMED;

FURTHER ORDERED that the decision of the Examiner rejecting claims 46-48 and 50 under 35 U.S.C. § 112, first paragraph, for lack of enablement is REVERSED;

FURTHER ORDERED that the decision of the Examiner rejecting claims 46-48 and 50 under 35 U.S.C. § 251 as improperly broadening the scope of the claims of Patent 5,601,997 is REVERSED; and,

FURTHER ORDERED that the case be returned to the Examiner for action consistent herewith.

AFFIRMED

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